IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner: L. Di Nola Baron Group Art Unit: 1615

Re: Application of: Stanley STEIN et al.

Serial No.: 09/883,842

Filed: June 18, 2001

For: **MULTIPLE PHASE CROSS-LINKED COMPOSITIONS AND USES THEREOF**

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

April 20, 2004

S i r:

In accordance with Applicant's duty of disclosure under 37 C.F.R.§1.56 and the provisions of 37 C.F.R. §§ 1.97 and 1.98, Applicants hereby make of record the documents listed on the accompanying PTO-1449 Form for consideration by the Examiner in connection with the examination of the above-identified patent application.

Copies of the references listed on pages 1-4 of the PTO-1449 Form are included herewith. If it is determined that any of the listed references are not included herewith, the Examiner is requested to contact the undersigned so that a copy can be forwarded. While the references are being submitted herewith, some or all of the references may not constitute prior art under the U.S. patent laws.

This Information Disclosure Statement is filed after a Request for Continued Examination. Accordingly, it is believed that no fee is due. However, if it is determined that any fee is due, the Examiner is authorized to charge said fee to Attorney Deposit Account No. 50-0552.

It is respectfully requested that the references cited on the accompanying PTO Form-1449 be considered and made of record.

Respectfully submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

By: _____

Robert J. Paradiso
Reg. No. 41,240

Davidson, Davidson & Kappel, LLC
485 Seventh Avenue, 14th Floor
New York, New York 10018
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FORM PTO-1083

Docket No.: 614/1009
Date: April 20, 2004

COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, VA 22313-1450

In re application of: Stanley STEIN, et al.
Serial No.: 09/883,842
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For: **MULTIPLE PHASE CROSS-LINKED COMPOSITIONS AND USES THEREOF**

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Transmitted herewith is a **Information Disclosure Statement** in the above-identified application.

[ ] Small entity status under 37 C.F.R. 1.9 and 1.27 has been previously established.
[ ] Applicants assert small entity status under 37 C.F.R. 1.9 and 1.27.
[X] No fee for additional claims is required.
[ ] A filing fee for additional claims calculated as shown below, is required:

	(Col. 1)	(Col. 2)		SMALL ENTITY		OR	LARGE ENTITY	
FOR:	REMAINING AFTER AMENDMENT	HIGHEST PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE	FEE		RATE	FEE
TOTAL CLAIMS	* Minus** =	0		x $ 9	$		x $ 18	$
INDEP. CLAIMS	* Minus*** =	0		x $ 42	$		x $ 84	$
[ ] FIRST PRESENTATION OF MULTIPLE DEP. CLAIM				+ $140	$		+ $280	$
				TOTAL:	$	OR	TOTAL:	$

* If the entry in Co. 1 is less than the entry in Col. 2, write "0" in Col. 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space.

[X] Also transmitted herewith are:
[ ] Petition for three (3) month extension under 37 C.F.R. 1.136
[X] Other: **Form PTO-1449 with cited references**

[ ] Check(s) in the amount of **$0.00** is/are attached to cover:
[ ] Filing fee for additional claims under 37 C.F.R. 1.16
[ ] Petition fee for extension under 37 C.F.R. 1.136
[ ] Other:

[X] The Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 50-0552.

[X] Any filing fee under 37 C.F.R. 1.16 for the presentation of additional claims which are not paid by check submitted herewith.
[X] Any patent application processing fees under 37 C.F.R. 1.17.
[X] Any petition fees for extension under 37 C.F.R. 1.136 which are not paid by check submitted herewith, and it is hereby requested that this be a petition for an automatic extension of time under 37 CFR 1.136.

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I hereby certify that this correspondence and/or documents referred to as attached therein and/or fee are being deposited with sufficient postage to the United States Postal Service as "first class mail" in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" on April 20, 2004.
DAVIDSON, DAVIDSON & KAPPEL, LLC

BY:

FORM PTO-1449 (REV. 7-80)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO.: 614.1009	SERIAL NO.: 09/883,842
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)		APPLICANT(S): Stanley STEIN, et al.	
		FILING DATE: June 18, 2001	GROUP: 1615

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
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FOREIGN PATENT DOCUMENTS

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OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	AC	T.G. Burke, A.K.Mishra, M.C.Wani, and M.E.Wall, Lipid bilayer partitioning and stability of camptothecin drugs, Biochemistry 32:5352-5364 (1993).
	AD	B. B. Lundberg. Biologically active camptothecin derivatives for incorporation into liposomes bilayers and lipid emulsions, Anticancer Drug Des., 13:453-461 (1998).
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	AN	V.R. Caiolfa, M. Zamal, A. Fiorino, E. Frigerio, C. Pellizzoni, R.d'Argy, A. Ghiglieri, M.G. Castelli, M. Farao, E. Present, M. Gigli, F. Angelucci, and A. Suarato, Polymer-bound camptothecin: initial biodistribution and antitumor activity studies, J. Control Release 65:105-119 (2000).

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	BC	J.W. Singer, P.De Vries, R. Bhatt, J. Tulinsky, P. Klein, C. Li, L. Milas, R.A. Lewis, and, S. Wallace, Conjugation of camptothecins to poly-(L-glutamic acid), Ann.N.Y.Acad.Sci. 922:136-150 (2000).
	BD	J.W. Singer, R. Bhatt, J. Tulinsky, K.R. Buhler, E. Heasley, P. Klein, and P. De Vries, Water-soluble poly-(L-glutamic acid)-Gly-camptothecin conjugates enhance camptothecin stability and efficacy in vivo, J. Control Release 74:243-247 (2001).
	BE	P.Tardi, E.Choice, D.Masin, T.Redelmeier, M.Bally, and T.D.Madden, Liposomal encapsulation of topotecan enhances anticancer efficacy in murine and human xenograft models, Cancer Res. 60:3389-3393 (2000).
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	BG	S.H. Jang, M.G. Wientjes, D. Lu, and J.L. Au., Drug delivery and transport to solid tumors, Pharm. Res., 20:1337-1350 (2003).
	BH	A.S. Hoffman, Hydrogels for biomedical applications, Advanced Drug Delivery Reviews, 43:3-12 (2002).
	BI	S.W. Kim, Y.H. Bae, and T. Okano, Hydrogels: swelling, drug loading, and release, Pharm.Res. 9:283-290 (1992).
	BJ	N.A.Peppas, P. Bures, W. Leobandung, and H. Ichikawa, Hydrogels in pharmaceutical formulations, Eur.J.Phar.Biopharm. 50:27-46 (2000).
	BK	R. J. Stenekes, A. E. Loebis, C.M. Fernandes, D.J. Crommelin, and W. E. Hennink. Degradable dextran microspheres for the controlled release of liposomes, Int. J. Pharm., 214:17-20 (2001).
	BL	K.S. Anseth, A.T. Metters, S.J. Bryant, P.J. Martens, J.H. Elisseeff, and C.N. Bowman, In situ forming degradable networks and their application in tissue engineering and drug delivery, J. Control Release 78:199-209 (2002).
	BM	X. Huang and C.S. Brazel, On the importance and mechanisms of burst release in matrix-controlled drug delivery systems, J. Control Release 73:121-136 (2001).
	BN	R. Jeyanthi, B. Nagarajan, and K. P. Rao. Solid tumour chemotherapy using implantable collagen-poly (HEMA) hydrogel containing 5-fluorouracil, J. Pharm. Pharmacol., 43:60-62 (1991).
	BO	C.J. de Groot, J.A. Cadee, J.W. Koten, W.E. Hennink, and W. den Otter. Therapeutic efficacy of IL-2-loaded hydrogels in a mouse tumor model, Int.J. Cancer, 98:134-140 (2002).
	BP	M. St'astny, D. Plocova, T. Etrych, K. Ulbrich, and B. Rihova. HPMA-hydrogels result in prolonged delivery of anticancer drugs and are a promising tool for the treatment of sensitive and multidrug resistant leukaemia, Eur. J. Cancer, 38:602-608 (2002).

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OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	CC	K.H. Bouhadir, E. Alsberg, and D.J. Mooney. Hydrogels for combination delivery of antineoplastic agents, Biomaterials, 22:2625-2633 (2001).
	CD	H. Okino, Y. Nakayama, M. Tanaka, and T. Matsuda, In situ hydrogelation of photocurable gelatin and drug release, J. Biomed.Mater.Res. 59:233-245 (2002).
	CE	N.A. Peppas, K.B. Keys, M. Torres-Lugo, and A.M. Lowman, Poly(ethylene glycol)-containing hydrogels in drug delivery, J. Control Release 62:81-87 (1999).
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	CG	J.A. Cadee, C.J. de Groot, W. Jiskoot, W. den Otter, and W.E. Hennink, Release of recombinant human interleukin-2 from dextran-based hydrogels, J. Control Release 78:1-13 (2002).
	CH	W.E. Hennink, O. Franssen, W.N.E. van Dijk-Wolthuis, and H. Talsma, Dextrans hydrogels for the controlled release of proteins, J. Control Relase 48:107-114 (1997).
	CI	M. Sen and A. Yakar, Controlled release of antifungal drug terbinafine hydrochloride from poly(N-vinyl 2-pyrrolidone/itaconic acid) hydrogels, Int.J.Pharm. 228:33-41 (2001).
	CJ	V.Subr, R.Duncan, and J.Kopecek, Release of macromolecules and daunomycin from hydrophilic gels containing enzymatically degradable bonds, J.Biomater.Sci.Polym.Ed 1:261-278 (1990).
	CK	E.Ruel-Gariepy, G.Leclair, P.Hildgen, A.Gupta, and J.C.Leroux, Thermosensitive chitosan-based hydrogel containing liposomes for the delivery of hydrophilic molecules, J.Control Release 82:373-383 (2002).
	CL	A. Paavola, I.Kilpelainen, J. Yliruusi, and P.Rosenberg, Controlled release injectable liposomal gel ibuprofen for epidural analgesia, Int.J.Pharm. 199:85-93 (2000).
	CM	A.Bochot, E.Fattal, A.Gulik, G.Couarraze, and P.Couvreaur, Liposomes dispersed within a thermosensitive gel: a new dosage form for ocular delivery of oligonucleotides, Pharm.Res. 15:1364-1369 (1998).
	CN	R.J. Stenekes, A.E. Loebis, C.M. Fernandes, D.J. Crommelin, and W.E. Hennink. Controlled release of liposomes from biodegradable dextran microspheres: a novel delivery concept, Pharm. Res., 17:690-695 (2000).

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							YES	NO
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OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	DC	N.O. Dhoot and M.A. Wheatley. Microencapsulated liposomes in controlled drug delivery: strategies to modulate drug release and eliminate the burst effect, J. Pharm. Sci., 92:679-689 (2003).
	DD	S.Vemuri and C.T.Rhodes, Preparation and characterization of liposomes as therapeutic delivery systems: a review, Pharm.Acta Helv. 70:95-111 (1995).
	DE	A. Sharma and U.S.Sharma, Liposomes in drug delivery: progress and limitations, Int.J.Pharm. 154:123-140 (1997).
	DF	P.Crosasso, M.Ceruti, P.Brusa, S.Arpicco, F.Dosio, and L.Cattel, Preparation, characterization and properties of sterically stabilized paclitaxel-containing liposomes, J.Control Release 63:19-30 (2000).
	DG	A.Sharma and R.M.Straubinger, Novel taxol formulations: preparation and characterization of taxol-containing liposomes, Pharm.Res. 11:889-896 (1994).
	DH	S.B.Kulkarni, G.V.Betageri, and M.Singh, Factors affecting microencapulation of drugs in liposomes, J.Microencapsul. 12:229-246 (1995).
	DI	S.Vemuri and C.T.Rhodes, Development and characterization of a liposome preparation by a pH-gradient method, J.Pharm.Pharmacol. 46:778-783 (1994).
	DJ	L.D.Mayer, L.C.Tai, M.B.Bally, G.N.Mitilenes, R.S.Ginsberg, and P.R.Cullis, Characterization of liposomal systems containing doxorubicin entrapped in response to pH gradients, Biochim.Biophys.Acta 1025:143-151 (1990).
	DK	D.B.Fenske, K.F.Wong, E.Mauer, N.Maurer, J.M.Leenhouts, N.Boman, L.Amankwa, and P.R.Cullis, Ionophore-mediated uptake of ciprofloxacin and vincristine into large unilamellar vesicles exhibiting transmembrane ion gradients, Biochim.Biophys.Acta 1414:188-204 (1998).
	DL	S.Clerc and Y.Barenholz, Loading of amphipathic weak acids into liposomes in response to transmembrane calcium acetate gradients, Biochim.Biophys.Acta 1240:257-265 (1995).
	DM	T.Lian and R.J.Ho, Trends and developments in liposome drug delivery systems, J.Pharm.Sci. 90:667-680 (2001).
	DN	H. Talsma and D.J.A. Crommelin, Liposomes as drug delivery systems, Part II: Characterization, Pharm. Tech., 52-58 (1992).
	DO	H. Talsma and D.J.A.Crommelin, Liposomes as drug delivery systems, Part III: Stabilization, Pharm. Tech., 48-59 (1993).
	DP	D. Subramanian and M.T. Muller, Liposomal encapsulation increases the activity of the topoisomerase I inhibitor topotecan, Oncol.Res. 7:461-469 (1995).
	DQ	B. Qiu, S. Stefanos, J. Ma, A. Lalloo, B.A. Perry, M.J. Leibowitz, P.J. Sinko, and S. Stein, A hydrogel prepared by in situ cross-linking of a thiol-containing poly(ethylene glycol)-based copolymer: a new biomaterial for protein drug delivery, Biomaterials 24:11-18 (2003).

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	BM	X. Huang and C.S. Brazel, On the importance and mechanisms of burst release in matrix-controlled drug delivery systems, J. Control Release 73:121-136 (2001).
	BN	R. Jeyanthi, B. Nagarajan, and K. P. Rao. Solid tumour chemotherapy using implantable collagen-poly (HEMA) hydrogel containing 5-fluorouracil, J. Pharm. Pharmacol., 43:60-62 (1991).
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EXAMINER	DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.